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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte IIPO ASKO JULIUS KOSKELA,
CHARLES MOUGENOT, and MARKO TAPANI HÄKKINEN

Appeal 2017-000570
Application 14/366,508¹
Technology Center 3700

Before DEMETRA J. MILLS, FRANCISCO C. PRATS, and
DEBORAH KATZ, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134(a) involves claims to processes of delivering therapeutic ultrasound energy to patients in a manner that avoids damaging tissue in a protected zone. The Examiner rejected the claims as being ineligible for patenting, and also for obviousness.

We have jurisdiction under 35 U.S.C. § 6(b).

We affirm the rejection for patent ineligibility, but reverse the obviousness rejection.

¹ Appellants identify Koninklijke Philips Electronics N. V. as the real party in interest. Appeal Br. 2.

STATEMENT OF THE CASE

The Specification discloses, as background to Appellants' invention, that "the use of high intensity focused ultrasound is currently being used as an approach for thermal therapeutic intervention for uterine fibroids and has been examined for possible uses in the treatment of the liver, the brain, and the prostate." Spec. 1.

The Specification explains that, in high intensity focused ultrasound, "an array of transducer elements are used to form an ultrasonic transducer By controlling the phase of alternating current electrical power supplied to each of the transducer elements[,] the focal point or target volume into which the ultrasound power is focused may be controlled." *Id.*

The Specification discloses, however, that "the ultrasound from individual transducer elements to the focal point the ultrasound can also add constructively and destructively. This can lead to hot spots or regions which are unintentionally heated or sonicated. There is therefore the risk that sensitive anatomical regions can be unintentionally injured during a sonication." *Id.*

In that regard, the Specification notes that United States Patent 7,699,780 B2 describes a method of delivering ultrasound energy in which the tissue targeted for treatment receives ultrasound energy at or above a prescribed intensity level, whereas "the energy intensity in a tissue region to be protected within the ultrasound energy path is at or below a prescribed safety level." *Id.* at 1–2.

In describing Appellants' invention, the Specification states:

This invention describes an algorithm for choosing the active [transducer] elements in a tightly controlled way, without compromises on the safety of the patient. According to the

invention, the sensitive regions are identified and marked, and a safety level is associated with each sensitive region. The intensity exposure on each sensitive region is estimated based on the incoherent and maximally coherent sum of the estimated intensities from transducer elements. Elements are turned off until the estimated ultrasound exposure is below safety level on all sensitive regions.

Id. at 18–19.

As to the “incoherent sum,” the Specification states:

As used herein an incoherent sum of the ultrasonic pressure generated by each of the multiple transducer elements encompasses calculating the ultrasonic pressure generated by each of the multiple transducer elements and squaring it then adding the values together. This sum is labeled the incoherent sum because the phases are not taken into consideration.

Id. at 6.

The Specification states that certain advantages may be obtained when using the incoherent sum to determine which transducers elements should be employed during treatment:

[The incoherent sum] has the benefit of producing a good estimate of the maximum ultrasonic intensity which can be generated within the protected zone. It is however much computationally less intensive than calculating a value which takes into account the coherent sum or the phases. Also there may be insufficient knowledge of the internal anatomy of the subject or the ultrasonic properties of the internal anatomy. Using the incoherent sum eliminates the possibility that a hot spot would be generated by the ultrasound and incorrectly calculated as being a point of low ultrasonic intensity. Using the incoherent sum may produce an estimate of the ultrasonic intensity which can be reasonably relied upon in a clinical setting.

Id.

Claim 15 is representative of the appealed subject matter and reads as follows:

15. A method of operating a medical instrument comprising a high intensity focused ultrasound system, the high intensity focused ultrasound system comprising:

an ultrasonic transducer, the ultrasonic transducer comprising a plurality of transducer elements; and

an electrical power supply connected to each of the plurality of transducer elements, wherein the electrical power supply provides electrical power,

wherein the high intensity focused ultrasound system is arranged for connecting and disconnecting the electrical power supply to each of the plurality of transducer elements,

wherein the method comprises acts of:

receiving a treatment plan specifying a protected zone within a subject;

calculating a set of transducer control parameters using the treatment plan such that an ultrasonic intensity estimate in the protected zone is below a predetermined threshold,

wherein the set of transducer element states specify the connecting and disconnecting the electrical power supply to each of the plurality of transducer elements,

wherein the ultrasonic intensity estimate is calculated using an incoherent sum of the ultrasonic pressure generated by each of the plurality of transducer elements; and

output control signals to selectively connect and disconnect the electrical power supply to each of the plurality of transducer elements based on the set of transducer control parameters.

Appeal Br. 23–24 (emphasis added).

The following rejections are before us for review:

(1) Claims 1–20, as being directed to subject matter ineligible for patenting (Ans. 2–4); and

(2) Claims 1–20, under 35 U.S.C. § 103(a), as being unpatentable over Vitek² and Liu³ (*id.* at 4–8).

PATENT ELIGIBILITY

The Examiner's Position

The Examiner determines that claims 1–20 are “directed to calculating ultrasound intensity using coherent [sic, incoherent] sum multiplied by a coherence factor which is an algorithm/mathematical relationship fundamental in the ultrasound field for some intended use [i.e. adjusting or planning treatment].” Ans. 2–3 (second pair of brackets in original). The Examiner determines, moreover, that the additional claimed elements, beyond the calculation of ultrasound energy, “do not provide meaningful limitations to transform the abstract idea into a patent eligible application of the abstract idea such that the claims amount to significantly more than the abstract idea itself.” *Id.* at 3

In particular, the Examiner reasons that the “abstract idea of calculating ultrasound intensity can be considered to be a fundamental algorithm/mathematical concept that allow[s] adjustment and determination of different elements for various intended use,” and the additional elements, “such as the generically cited ultrasonic transducer, processor, power supply, memory ... do not add a meaningful limitation as they are used

² US 2006/0058671 A1 (published Mar. 16, 2006).

³ US 2006/0173313 A1 (published Aug. 3, 2006).

conventionally and routinely for transmitting, processing and storing data during ultrasound procedures.” *Id.*

The Examiner further reasons as follows:

Essentially, the claimed invention, not requiring a particular machine, applies the abstract idea on a generic control unit/processor - i.e., reads on mental activity – to perform well-understood, routine and conventional acts in the art [e.g., calculating a quantity (intensity) of natural phenomenon to distinguish elements that are related to the natural phenomenon (ultrasound pressure and ultrasound intensity are natural phenomenon)]. The claims also do not recite any means/steps of improvements to a technological field with the generic recitations; and/or improvements to the functioning of the computer. All of the aforementioned weigh against patentability.

Id. (brackets in original).

Analysis

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

[T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .

After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

Having carefully considered the arguments and evidence advanced by Appellants and the Examiner, we are not persuaded that a preponderance of the evidence fails to support the Examiner’s conclusion that the rejected claims recite subject matter ineligible for patenting.

35 U.S.C. § 101 states that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any

new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

The Supreme Court has “long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable.” *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 134 S.Ct. 2347, 2354 (2014).

Our reviewing court has summarized the Supreme Court’s two-part test for distinguishing between claims to patent-ineligible exceptions, and claims to patent-eligible applications of those exceptions, as follows:

Step one asks whether the claim is “directed to one of [the] patent-ineligible concepts.” [*Alice*, 134 S.Ct. at 2354]. If the answer is no, the inquiry is over: the claim falls within the ambit of § 101. If the answer is yes, the inquiry moves to step two, which asks whether, considered both individually and as an ordered combination, “the additional elements ‘transform the nature of the claim’ into a patent-eligible application.” *Id.* (quoting *Mayo [Collaborative Services v. Prometheus Labs, Inc.]*, 132 S.Ct. 1289, 1297 (2012)).

Step two is described “as a search for an ‘inventive concept.’” *Id.* (quoting *Mayo*, 132 S.Ct. at 1294). At step two, more is required than “well-understood, routine, conventional activity already engaged in by the scientific community,” which fails to transform the claim into “significantly more than a patent upon the” ineligible concept itself. *Mayo*, 132 S.Ct. at 1298, 1294.

Rapid Litigation Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1047 (Fed. Cir. 2016) (paragraphing added).

As to step one, our reviewing court has explained that “the ‘directed to’ inquiry applies a stage-one filter to claims, considered in light of the specification, based on whether ‘their character as a whole is directed to excluded subject matter.’” *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327,

1335 (Fed. Cir. 2016) (citing *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015)). Thus, the step one analysis required by *Alice* “inquir[es] into ‘the focus of the claimed advance over the prior art.’” *Id.* (citing *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1375 (Fed. Cir. 2016)).

In the present case, as seen from the summary of Appellants’ Specification presented above, Appellants’ invention is not directed to improving the components of prior art ultrasound systems. Rather, as explained in the Specification, Appellants’ invention is directed to methods for calculating the amount of energy that the ultrasound system applies to a patient, in order to avoid damaging tissue that requires protection during treatment. *See Spec.* 18–19 (“This invention describes an algorithm for choosing the active [transducer] elements in a tightly controlled way, without compromises on the safety of the patient.”); *id.* at 19 (“The intensity exposure on each sensitive region is estimated based on the incoherent and maximally coherent sum of the estimated intensities from transducer elements.”).

In claiming that invention, representative claim 15 recites the steps of (a) “receiving a treatment plan specifying a protected zone within a subject,” and (b) “calculating a set of transducer control parameters using the treatment plan such that an ultrasonic intensity estimate in the protected zone is below a predetermined threshold.” Appeal Br. 24.

Claim 15 specifies that “the ultrasonic intensity estimate is calculated using an incoherent sum of the ultrasonic pressure generated by each of the plurality of transducer elements.” *Id.* Claim 15 recites that the calculated

treatment plan may be executed by connecting and disconnecting the individual ultrasound elements according to the plan. *Id.*

Accordingly, viewing claim 15 in light of the Specification, we agree with the Examiner that the claimed invention is directed to the abstract idea of using the incoherent sum of the ultrasonic pressure generated by each of the plurality of transducer elements to calculate the amount of energy that the ultrasound system applies to a patient, in order to avoid damaging tissue that requires protection during treatment.

We acknowledge, as Appellants contend (Appeal Br. 11–12), that claim 15 recites the use of an ultrasound system, i.e., a specific machine. We acknowledge also that ultrasound systems kill, i.e., transform, targeted cells. *Id.* at 12; Reply Br. 6–7.

As our reviewing court has explained, however, “not every claim that recites concrete, tangible components escapes the reach of the abstract-idea inquiry.” *In re TLI Communications LLC Patent Litigation*, 823 F.3d 607, 611 (Fed. Cir. 2016). In particular, in *TLI Communications*, the court noted that claims that reciting general-purpose computer components, a “scanner,” an “interface,” “network,” and a “database” were nevertheless “directed to” an abstract idea. *Id.* (citing *Alice*, 134 S.Ct. at 2360; *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat’l Assn.*, 776 F.3d 1343, 1347 (Fed. Cir. 2014); *Mortg. Grader, Inc. v. First Choice Loan Serv. Inc.*, 811 F.3d 1314, 1324–25 (Fed. Cir. 2016)).

As discussed above, when viewed in light of the Specification, it is evident that claim 15 is directed to the abstract idea of using the incoherent sum of the ultrasonic pressure generated by each of the plurality of transducer elements to calculate the amount of energy that the ultrasound

system applies to a patient. That is, claim 15 is directed to the abstract idea of determining, through mathematical calculation, how to use the ultrasound system, rather than an improvement in the components of the actual system.

Accordingly, that claim 15 recites the use of an ultrasound system that may be used to kill target cells does not persuade us that claim 15 is not directed to an abstract idea, under the step one inquiry required by *Alice*. See *TLI Communications*, 823 F.3d at 613 (“[A]lthough the claims limit the abstract idea to a particular environment—a mobile telephone system—that does not make the claims any less abstract for the step 1 analysis.”); see also *Bilski v. Kappos*, 561 U.S. 593, 605–606 (2010) (machine-or-transformation test not dispositive as to patent eligibility).

Turning to step two of the *Alice* inquiry, Appellants do not persuade us that claim 15, outside of the ineligible abstract idea, recites an inventive concept which is more than “well-understood, routine, conventional activity previously engaged in by researchers in the field.” *Mayo*, 132 S.Ct. at 1294.

As noted above, Appellants’ Specification discloses that ultrasound systems having multiple transducers as recited in claim 15 were known in the art. See Spec. 1. As noted above, the Specification also discloses, as recited in claim 15, that it was known in the art to formulate treatment plans for those ultrasound systems which avoided harming tissue for which protection was desired. See *id.* at 1–2 (citing U.S. Patent No. 7,699,780 B2 (“the ’780 patent”)). We note in particular that the Vitek patent applied in the obviousness rejection discussed below is the initial publication of the application upon which the ’780 patent is based. Compare the ’780 patent cover page (application no. 10/916,998) to Vitek cover page (application no. 10/916,998). Accordingly, on the current record, as underscored below in

the discussion regarding the obviousness rejection, the elements of the apparatus recited in claim 15, as well as how those elements are used in the claim to protect tissue during operation, were known activities already engaged in by skilled artisans.

Moreover, because claim 15's process involves receiving and then mathematically manipulating information for subsequent use by a conventional prior art apparatus, the claimed process is analogous to that at issue in *Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350, 1351–52 (Fed. Cir. 2016). As the court in *Electric Power Group* explained in relation to step two of the *Alice* inquiry, “limiting the claims to the particular technological environment [at issue] is, without more, insufficient to transform them into patent-eligible applications of the abstract idea at their core.” *Id.* at 1354. Thus, because claim 15's process, outside of the ineligible abstract idea of using the incoherent sum for calculating ultrasound intensity, only employs known elements involved in the specific technological environment of therapeutic ultrasound, Appellants do not persuade us that claim 15 contains something more, outside of the ineligible concept, that renders the claim patent eligible.

Appellants contend that using the incoherent sum improves the process by making it safer. Appeal Br. 10–11; Reply Br. 5–6. In that regard, we acknowledge the Specification's prophetic disclosure that using the incoherent sum “*may be* safer than a system which uses a coherent sum of the pressures to predict the location of unintentional heating zones.” Spec. 2 (emphasis added).

We note again, however, that ultrasound methods that protect untreated tissue from damage were known in the art. *See, e.g.*, Spec. 1–2

(citing the '780 patent); *see also* Vitek, abstract. Appellants do not identify on the current record any specific evidence, comparative or otherwise, persuasively demonstrating that using the incoherent sum when calculating an ultrasound treatment plan is any safer than the prior art methods of record, which, like claim 15 protect untreated tissue from undesired damage.

Appellants contend that using the incoherent sum improves the performance of the ultrasound system, because the incoherent sum is easier to calculate than the coherent sum. Reply Br. 3. Representative claim 15, however, does not include a processor, and therefore encompasses performing the calculation mentally. Appellants do not explain persuasively how performing a calculation mentally will improve, or even change, how the claimed ultrasound system functions.

Moreover, even assuming that the incoherent sum is easier to calculate for a system that uses a processor to perform the calculation, the alleged improvement still ultimately remains in the ineligible abstract idea. That the calculation might be different does not demonstrate a difference in how the processor functions, or how the ultrasound system ultimately delivers ablative therapy while protecting untreated tissue. Thus, although the claimed abstract calculation might be better than other abstract calculations known in the art for controlling the claimed set of conventional elements, that fact does not persuade us that, taking the claim elements as a whole, the claimed invention includes an inventive concept beyond the claimed ineligible abstract idea, as required under step two of *Alice*.

In sum, for the reasons discussed, Appellants do not persuade us that, under the two-step inquiry set forth in *Alice*, the preponderance of the evidence fails to support the Examiner's determination that the process

recited in claim 15 is directed to subject matter ineligible for patenting. We, therefore, affirm the Examiner's rejection of claim 15 on that ground. Claims 1–14 and 16–20 fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

OBVIOUSNESS

The Examiner's Prima Facie Case

In rejecting claims 1–20, the Examiner cited Vitek as teaching or suggesting instruments, computer readable media, and processes having nearly all of the steps and features recited in the rejected claims, but found that Vitek differed from the rejected claims in that “Vitek does not explicitly disclose wherein the ultrasonic intensity estimate is calculated using an incoherent sum of the ultrasonic pressure generated by each of the plurality of transducer elements” as recited in each of independent claims 1, 14, and 15. Ans. 5.

The Examiner found, however, that “Vitek's instrument is capable of estimating ultrasonic intensity by using an incoherent sum of the ultrasonic pressure generated by each of the multiple transducer elements. Vitek discloses calculating intensity of multiple transducer elements (see [0037-0038] and [0043]).” *Id.* at 5–6. The Examiner determined, moreover, that “[t]here are different ways of estimating/calculating ultrasound intensity and it only require[s] routine skill in the art to estimate/calculate ultrasound intensity.” *Id.* at 6.

As to using the incoherent sum when calculating the ultrasound intensity generated in Vitek's system, the Examiner found that “Liu explicitly discloses estimat[ing] ultrasound intensity by incoherent sum (see [0036]; the incoherent data is summing the intensity).” *Id.*

Based on the references' combined teachings, the Examiner concluded that an ordinary artisan would have considered it obvious "to calculate ultrasound intensity by incoherent sum of the ultrasonic pressure generated by each of the multiple transducer elements as taught by Liu because this is one of many effective ways to calculat[e] the ultrasound intensity of the multiple transducer elements and only require routine skill in the art." *Id.*

Analysis

It is well settled that, "[i]n proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art." *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992).

In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), although the Supreme Court emphasized "an expansive and flexible approach" to the obviousness question (*id.* at 415), it also reaffirmed the importance of determining "whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue." *Id.* at 418 (emphasis added).

Thus, "[o]bviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination." *Unigene Laboratories, Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011).

Instead, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill

in the art.” *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

Having carefully considered the arguments and evidence advanced by Appellants and the Examiner, Appellants persuade us that a preponderance of the evidence does not support the Examiner’s conclusion of obviousness. In particular, we agree with Appellants (*see, e.g.*, Appeal Br. 17) that the Examiner has not persuasively shown that the combination of Vitek and Liu would have suggested using the incoherent sum of the ultrasonic pressures of each of Vitek’s transducer elements when formulating a treatment plan, as recited in each of independent claims 1, 14, and 15 (*see id.* at 20, 23, 24).

We acknowledge, as the Examiner found, and as required by Appellants’ claims, that Vitek discloses using ultrasound to treat target tissue, while protecting sensitive untreated tissue from damage. Vitek, abstract. Vitek explains that “ultrasound systems have been used for treating tissue, e.g., by directing acoustic energy towards a target tissue region within a patient, such as a cancerous or benign tumor, to coagulate, necrose, generate mechanical damage (by cavitation) or otherwise heat the tissue region.” *Id.* ¶ 2.

As the Examiner found, Vitek explains that a treatment plan that ablates target tissue, but protects other tissue, determines the ultrasound energy intensity that will be applied to the various locations of the tissue, “preferably includ[ing] operational parameter(s), e.g., phase, amplitude, etc., for each of the transducer elements” (*id.* ¶ 35), as well as the relative positions of the transducers and the target and non-target/protected tissues (*id.* ¶¶ 36–38). In certain embodiments, as Appellants’ claims require, Vitek discloses that individual transducers can be turned off. *See id.* ¶ 38

(describing a “scenario in which the corresponding transducer element(s) 12 will not be activated by the controller 18 during an execution of the treatment plan”); *see also id.* ¶ 48 (protecting ribs from undesired ultrasound application by “turn[ing] off transducer elements directed at ribs, while activating transducer elements that are directed between ribs”).

In contrast to Vitek’s tissue-ablating methods, Liu is directed to using ultrasound for imaging, as Appellants contend. *See* Liu ¶ 1 (“This present invention relates to adapting ultrasound imaging as a function of coherence. In particular, imaging is performed as a function of the coherence of acquired data.”).

Liu describes generating a “coherence factor” for an ultrasound imaging system which can be used to modify attributes of images generated by the system:

A coherence factor is computed as a ratio of the energy of the coherent sum to the energy of the at-least-partially incoherent sum of these signals [from the transducer elements]. . . . In one embodiment coherence factor is used to modulate the gray level or color of the image synthesized using the component images.

Id. ¶ 13; *see also id.* ¶ 40 (“The coherence factor is calculated as a function of the coherent and incoherent sums. For example, the coherence factor is a ratio of energy of a coherent sum to energy of an incoherent sum.”).

As to the use of the incoherent sum in determining its coherence factor, Liu explains:

Incoherent summation (compounding) may suppress speckle and improve boundary depiction. The component images are formed using different transmit steering with possibly different receive aperture selection schemes, such as partially overlapping sub-apertures. Coherent factor information is computed using the component images corresponding to each transmit/receive aperture scheme. This coherence factor image

can then be used to modulate the compounded image in brightness or color.

Id. ¶ 44 (emphasis added); *see also id.* ¶ 45 (“Adding images incoherently helps reduce speckle.”).

Thus, Liu’s coherence factor, which uses the incoherent sum, is employed, essentially, to enhance image quality. *See id.* ¶ 44 (using coherence factor image to “modulate the compounded image in brightness or color”); ¶ 46 (registering coherence factor image on gray-scale image “helps identify which part of tissue is introducing more inhomogeneity in wave propagation”); ¶ 47 (using coherence factor when blending images together to produce an output).

We agree with Appellants that the Examiner has not explained adequately how using the incoherent sum to generate a mathematical function that enhances ultrasound image quality, as taught in Liu, would have prompted an ordinary artisan to use the incoherent sum when formulating a treatment plan for applying ablative ultrasound, as taught in Vitek. On the current record, the Examiner at best has shown that the individual elements of the claimed invention were known in the art. *See* Ans. 11–13. As discussed above, however, that is insufficient to establish *prima facie* obviousness. *See Unigene v. Apotex*, 655 F.3d at 1360.

In sum, we are not persuaded that the Examiner has advanced a sufficient reason that explains why Vitek and Liu would have suggested using the incoherent sum of the ultrasonic pressures of each of Vitek’s transducer elements when formulating a treatment plan, as recited in each of independent claims 1, 14, and 15. We, therefore, reverse the Examiner’s rejection of those claims, and their dependent claims, over those references.

SUMMARY

For the reasons discussed, we affirm the Examiner's rejection of claims 1–20, as being directed to subject matter ineligible for patenting.

However, for the reasons discussed, we reverse the Examiner's rejection of claims 1–20, under 35 U.S.C. § 103(a), as being unpatentable over Vitek and Liu.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED